

**County Alameda  
Public Health Department  
Emergency Medical Services Division**

**Trial Study  
The Prehospital Use of Fentanyl**

**18 Month Report**

**March 24, 2009**

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# **AN ANALYSIS OF THE PARAMEDIC ADMINISTRATION OF FENTANYL**

## **INTRODUCTION**

Pain is a common complaint in emergency medical services (EMS) patients. It is estimated that 14.8 million patients are transported by ambulance to emergency departments annually, and that 20 percent of them, approximately 2.9 million, have moderate to severe pain (McLean, Maio & Domeier, 2002, pp. 402- 405). In most EMS jurisdictions nationwide, paramedics manage pain with intravenous or intramuscular morphine sulfate (McManus & Sallee, 2005). Morphine sulfate has numerous side effects that include respiratory depression, hypotension, xerostomia, nausea and vomiting. Fentanyl and morphine are both counteracted by naloxone; however, fentanyl has a shorter onset of action, shorter duration, and far fewer side effects making it an appealing candidate for pre-hospital pain management. Little research exists regarding the use of fentanyl in the pre-hospital environment. Published studies show fentanyl to be a safe and effective alternative to morphine for out-of-hospital analgesia, citing a low clinical incidence of adverse reactions (Kanowitz, Dunn, Kanowitz, Dunn & VanBuskirk, 2006, pp. 1 - 7).

This study's intent is to prospectively assess the characteristics of the paramedic administration of fentanyl. Three transporting fire departments sought to determine if paramedics were able to adequately assess patient pain and safely utilize fentanyl to treat that pain in pediatric and adult patients. In addition the present study sought to retrospectively compare several clinical characteristics in patients treated with morphine sulfate to those within the fentanyl study group.

## **METHODS**

### **Design**

This was a prospective non-randomized study that compared select data to historical controls. Data for the patients who received fentanyl was compared to the patients who received morphine sulfate from an identical time period exactly one year prior. The design was approved by the Alameda County Medical Center/Alameda County Department of Public Health Institutional Review Board.

### **Setting**

Three municipal fire departments in Alameda County participated in this study: Berkeley Fire Department, Albany Fire Department, and Piedmont Fire Department. All three agencies provide advanced life support (ALS) transport services with ambulances staffed by two paramedics. The cities served by the three agencies range in population from 10,952, in Piedmont, to 102,743, in Berkeley, and Albany at 16,444. Combined, the three fire departments respond to approximately 9000 medical aid requests per year and they treat an estimated four percent of these patients with opioid analgesics. Pain management is provided by an ALS paramedic according to Alameda County EMS protocol during transport to the receiving hospital. The three city fire departments are components of the Alameda County EMS System.

In the State of California, morphine sulfate is the only option for EMS practitioners for pain management. Fentanyl is not a component of the state paramedic scope of practice. The California EMS Authority approved this investigation as a "pilot study" pursuant to Health and Safety Code, Division 25, Section 1797.221.

### **Population**

Between September 2007 and March 2009, patients received fentanyl if they presented with moderate to severe pain, requested pain control, and were six months old or greater. Moderate to severe pain was represented as a pain score of 4/10 or higher on any of the four pain scales used by the Alameda County EMS system. All findings and treatments were documented on a supplemental form specific to the fentanyl trial. Exclusion criteria included a history of renal or hepatic insufficiency, known opioid allergies, acute hemodynamic, respiratory, or neurological compromise, and head trauma. Patients who had already received opioid analgesics prior to paramedic arrival and patients whose care deviated from County or study protocols were also excluded. The researchers reviewed the charts of all patients who were treated with morphine by EMS personnel from the three fire departments between September 2006 and February 2007.

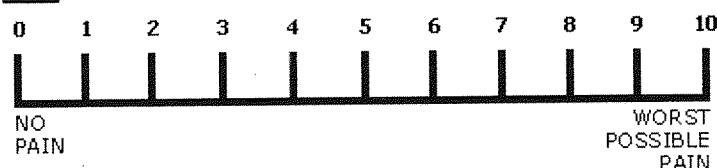
### **Intervention**

The study intervention consisted of the participating agencies paramedics attending a two hour training session which first reviewed patient pain assessment and separately fentanyl administration. The instructions covered documentation, Alameda County EMS pain management protocols, narcotic diversion, research data collection, and patient pain assessment scoring.

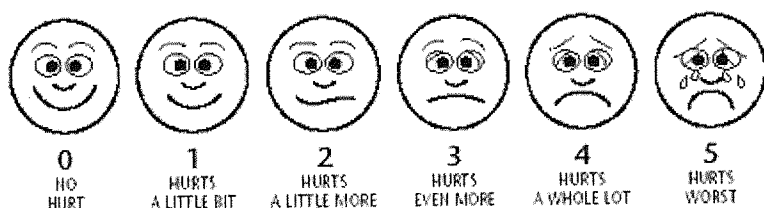
Paramedics utilized the Numeric Pain Scale (NPS) for all adult patients, the Wong Baker “Faces” scale for pediatrics, and the Face Legs Activity Cry Consolability scale (FLACC) for infants and children. Paramedics utilized the Pain Assessment in Advanced Dementia scale (PAINAD) for patients with dementia or cognitive impairment. All four scales provide pain scores ranging from 0 to 10. (See Figure 1.)

Figure 1.

### NPS



### Wong Baker Scale



### FLACC

Category	Scoring		
	1	2	3
Face	No Particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly normal position, moves easily	Squirming, shifting back and forth, tense	Arched, ridged or jerking
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs; frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort

## **PAINAD**

<b>Items</b>	<b>0</b>	<b>1</b>	<b>2</b>
<b>Breathing independent of vocalization</b>	Normal	Occasional labored breathing. Short period of hyperventilation.	Noisy labored breathing. Long period of hyperventilation. Cheyne – Stokes respirations.
<b>Negative vocalization</b>	None	Occasional moan or groan. Low level speech with a negative or disapproving quality.	Repeated troubled calling out. Loud moaning or groaning. Crying.
<b>Facial Expressions</b>	Smiling or inexpressive	Sad. Frightened. Frown.	Facial grimacing.
<b>Body Language</b>	Relaxed	Tense. Distressed pacing. Fidgeting.	Rigid. Fists clenched. Knees pulled up. Pulling or pushing away. Striking out.
<b>Consolability</b>	No need to console	Distracted or reassured by voice or touch.	Unable to console, distract or reassure.

The fentanyl was packaged in a concentration of 100 µcg/ 2 mL of normal saline, and paramedics administered fentanyl either IV or IM at 1 microgram per kilogram (1 µcg/kg) as a first dose for all included patients. Second and subsequent doses were repeated every 5 minutes at ½ the initial dose to a maximum of 3 µcg/kg, or until the patient was pain free or resting comfortably. Paramedics were directed to use half the dosage in patients over the age of 65 years. All patients were continuously monitored for changes in vital signs.

Paramedics completed a data collection form for every patient who received fentanyl (Table X).

### **Outcome Measures**

The primary outcome measure was the reduction of pain from the time of initial patient assessment to the transfer of the patient care to emergency department staff.

## **DATA COLLECTION AND ANALYSIS**

### **Population**

From September 2007 to November 2008 a total of 318 patients were administered fentanyl. The categorical analyses of those administrations were as follows:

- Trauma = 206 (65%)
- Medical = 98 (31%)
- Cardiac/CHF = 11 (3%)
- Burns = 3 (1%)

The age ranges of these patients were as follows:

- 0 – 15 = 14 (4%)
- 16 – 25 = 40 (13%)
- 26 – 45 = 94 (29%)
- 46 – 65 = 91 (29%)
- 66+ = 79 (25%)

Of the 318 patients who received fentanyl only three adverse reactions were reported; two reported dizziness (0.006%) and one reported nausea (0.003%). No vital sign abnormalities were noted and none required naloxone for reversal. Only one of the 318 patients reviewed was excluded from the study due to a paramedic protocol violation (Noted in discussion). No incidents of diversion were reported by any of the three participating fire departments.

### **Fentanyl vs. Morphine Comparison**

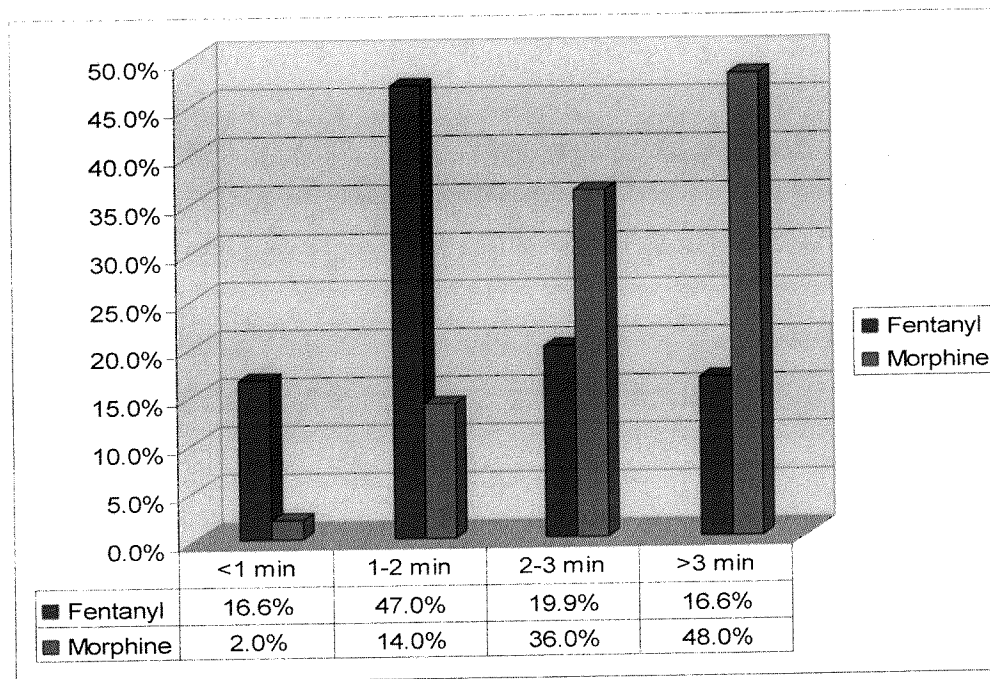
Of the 159 patients that received fentanyl during the documented time frame of September 1, 2007 to February 28, 2008, one (1) exclusion due to treatment error. 158 patients were compared to 83 patients one year prior who received morphine.

The retrospective chart review, found that 83 patients received morphine, but, due to poor patient assessments and documentation, by the treating paramedic, only 66 of the reported patient care reports contained usable data.

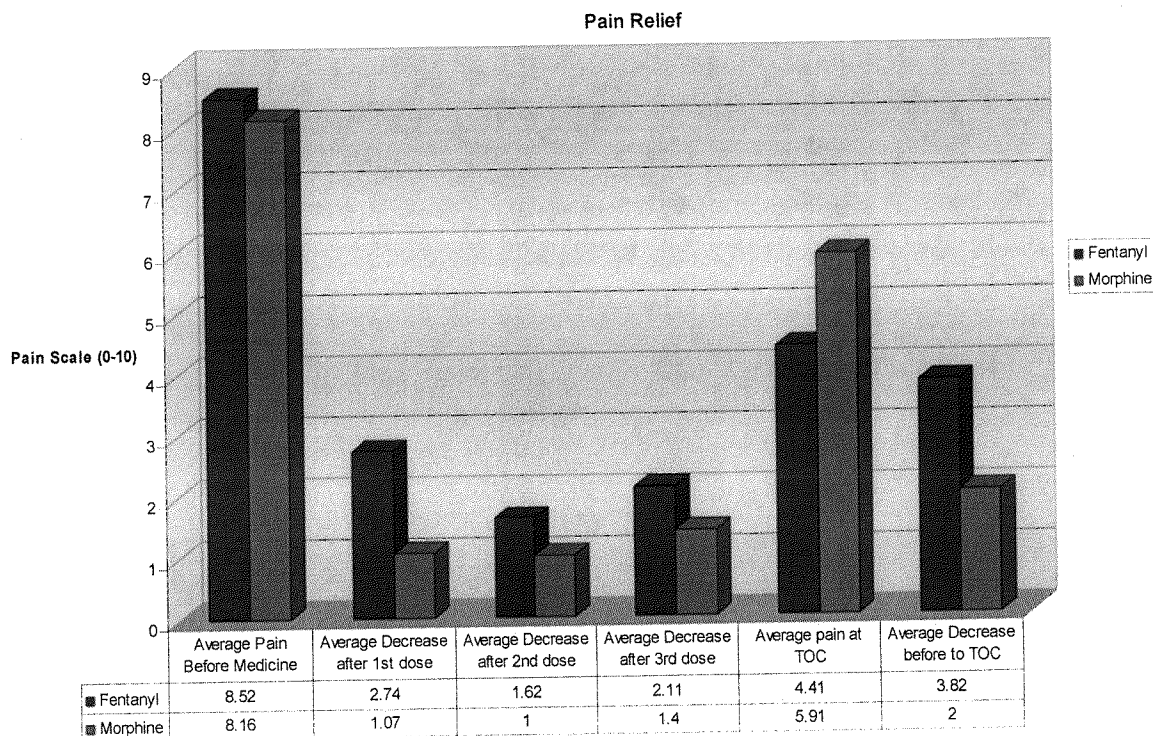
In this study, the onset of action for the reduction of patient pain was notably more rapid with fentanyl citrate than morphine sulfate. As displayed in figure 2, 16.6% of the patients that received fentanyl as compared to 2% morphine subjectively noted pain relief in under one (1) minute, 47% of fentanyl verses 14% of morphine at one (1) to two (2) minutes, 19.9% of fentanyl verses 36.0 % at two (2) to three (3) minutes, and 16.6% of fentanyl verses 48.0% of morphine at greater than three (3) minutes.

The reduction of pain, as noted on a one (1) to 10 pain scale in figure 3, was found to be almost double with fentanyl, 3.82 point pain reduction, as compared to morphine, two (2) point pain reduction, upon transfer of care (TOC) to the emergency department (ED).

As displayed in figure 2, the onset of action for the reduction of reported patient pain was significantly quicker for the patients that received fentanyl as compared to morphine.



As shown in figure 3, the average in pain per dose and average decrease in pain at transfer of care was found to be almost double in comparison to morphine.





## DISCUSSION

Our study found a significant increase in the use of Fentanyl, (n = 148), for pain management as compared to the retrospective review of morphine for the same allotted time period, of six (6) months, one year prior (n = 83). We feel that these findings can be attributed to the comprehensive re-enforcement and re-education of the EMS providers, regarding the significance of pain management, pain assessment, the dispelling of preconceived myths concerning the use of analgesics (McManus & Sallee, 2005), the efficacy of fentanyl, the modification of the Berkeley Fire Department Controlled Substance Policy 19.7, which strengthened narcotic security while allowing for simpler distribution for narcotic restock, and the Hawthorne effect (Mayo & Roethlisberger, 2008), through the instituted training exclusively for this study's purposes.

The retrospective review of morphine analgesic administration for patient pain re-enforces previous findings that prehospital providers fail to adequately, recognize, assess, and treat pain (DeVellis, Thomas & Wedel, 1998, pp. 293-296) (Basket, 1999, pp. 784-785) (McEachin, McDermott & Swor, 2002, pp. 406-410) (Alonso & Wesley, 2003, pp. 482-488) (Abbuhl & Reed, pp. 482-488). Jones and Machen's study of United Kingdom's emergency medical services (EMS) providers, found that the fear of adverse reactions was cited as a reason for withholding analgesia in the prehospital environment (Jones & Machen, pp. 166-172). Studies conducted by Ricard – Hibon et al, Verignon et al, and Fullerton – Gleason and Crandall, have proven that this perception is unfounded, displaying minimal to no incidents of adverse affects from prehospital analgesic administration (Ricard - Hibon et al, pp. 461-466) (Verignon, Degesves, Garcet, Magotteaux & Tramadol, 2001, pp. 1543-1546) (Gleason, Crandall & Sklar, pp. 411-416). Our study's findings had similar conclusions; one (1) incident of nausea, from 83 patients reviewed was noted from the administration of morphine sulfate. As previously discussed, only three (3) adverse responses, out of 318 cases, were reported from the administration of fentanyl, none experienced vital sign abnormalities, and none required recovery intervention. There were no admissions to the hospital, nor patient deaths attributed to the prehospital use of fentanyl. The statistical improvement in the patient subjective pain scales was also similar to Kanowitz's finding; Kanowitz 8.4 to 3.7, our trial 8.52 to 4.7. One case was excluded from the study due to protocol violations by the treating paramedic. The contributing factors for the violations were found to be multiple failures in the paramedic's ability to accurately differentiate between subjective and objective assessment findings and formulate an appropriate treatment plan. This paramedic was noted to have had similar issues of this nature in the past and was provided remediation and subsequently re-educated to the fentanyl trial. The previously mentioned patient experienced no adverse reactions or negative outcome from the fentanyl administration.

Even with the implementation of an extremely liberal Prehospital pain management protocol, Alameda County EMS Policies 7230 and 7316, only through continuous emphasis on pain education, pain research, and program monitoring development will the quality of pain assessment and management in the prehospital setting improve.

Braude and Richards have also cited four reasons for the expanded use of fentanyl citrate in the prehospital setting over morphine sulfate:

1. Fentanyl is more rapid acting narcotic than morphine. Its peak effect is reached within two (2) – three (3) minutes as compared to morphine's peak effect of approximately 15 minutes. If a repeat dose is given before the peak effect of the prior dose there is the risk of dose stacking and potential overdose.
2. Fentanyl has a duration of action of 30 minutes, where as morphine may last 3 – 4 hours. Fentanyl is less likely to cause prolonged sedation.
3. Fentanyl does not provoke histamine release and is less likely to produce a hypotensive response.
4. Fentanyl is also less likely to produce nausea and vomiting.

No reports of narcotic diversion were reported or found during the fentanyl study trial period. In preparation for the Prehospital Trial of Fentanyl, the Berkeley Fire Department implemented a new controlled substance policy, General Order 19.7, EMS Section. The general order is consistent with the provisions set forth by the Federal Drug Administration, Department of Justice, Drug Enforcement Agency, the Controlled Substance Act, and the California Health and Safety Code 11122.0. Berkeley Fire Department General Order 19.7 provides policies and procedures to obtain, secure, document, track the use of, and disposal of controlled substances. A copy of the general order is included with this document.

## **CONCLUSION**

The Prehospital Paramedic Administration of Fentanyl Trial Study reviewed the administration of fentanyl to 317 patients with findings similar to that of Kanowitz et al, with zero reports of diversion reported or discovered during patient chart, narcotic log review, and physical drug counts. Our conclusions echo that of Kanowitz et al; IV fentanyl can be used safely and effectively in the prehospital arena without causing significant hypotension, respiratory depression, hypoxemia, or sedation.

## **RECOMMENDATIONS**

It is recommended that the paramedic administration of IV fentanyl citrate be added to the Basic Paramedic Scope of Practice under Title 22, Article 2, Section 1001145, Part 1. Basic Scope of Practice or Part 2. Local Optional Scope of Practice.

This study, as supported by previous studies and literature, has shown that paramedics can safely and effectively administer fentanyl citrate in the prehospital setting without the complications of diversion.

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